American Association of Tissue Banks

The leader in support of quality, safety and availability of cells and tissue

24th Annual Meeting, September 9-12, 2000, Sheraton Bal Harbour, Florida

July 17, 2000

Kathy A. Eberhart
Office of Communications, Training
& Manufacturers Assistance
Division of Manufacturers Assistance and Training
Manufacturers Assistance & Technical Training Team
Center for Biologics Evaluation and Research (HFM-49)
11400 Rockville Pike, Rm. 315
Rockville, Maryland 20857

Dear Ms. Eberhart:

We are aware that FDA has posted on its web site an announcement of a public meeting concerning human bone allograft "in relation to FDA's proposed tissue rules." We are writing to request that the meeting, scheduled for August 2, 2000, be postponed to enable AATB adequate opportunity to prepare testimony and other information to assist FDA in its evaluation.

The American Association of Tissue Banks was formed in 1976 to help ensure that transplantable human tissues are safe, of uniform high quality, and supplied in quantities sufficient to meet national needs. The Association's membership currently includes 1,200 individual professionals, including many orthopedic surgeons who use allograft bone routinely in surgical practice.

Because of our members' keen interest in the complex scientific and regulatory issues relating to orthopedic uses of allograft bone, AATB would very much like to participate in the August 2 meeting. However, we have serious reservations about our ability to do so.

First, AATB learned of the meeting only recently by visiting FDA's web site because a notice announcing the meeting has not been published in the Federal Register. Two and a half weeks is not sufficient time for us to prepare testimony and information necessary to address the complex scientific issues associated with FDA regulation of allograft bone. Second, the president-elect of our Association, who is also an orthopedic surgeon and highly qualified to provide information to FDA on the use of bone allograft in surgical practice, is out of the country and thus unavailable to prepare a

1350 Beverly Road, Suite 220-A • McLean, Virginia 22101 • Web Site: http://www.aatb.org • Phone: 703-827-9582 • Fax: 703-356-2198 • email: aatb@aatb.org

presentation for the August 2 meeting. We are making efforts to identify other experts who might assist the Association in preparing for the meeting, but to date have been unsuccessful.

We are, therefore, requesting that FDA reschedule the August 2 meeting to a later date to enable AATB and its members better to prepare. In the event the meeting moves forward as scheduled, we will, at most, provide a brief statement with supplemental materials later submitted to the record, which we understand will be kept open until at least September 1, 2000. We believe we can be of valuable assistance to FDA as it develops policy in this area; it would be unfortunate if we were unable to participate fully due to a scheduling issue.

Sincerely yours,

P. Robert Rigney, Jr., J.D.
Chief Executive Officer

cc: Ruth R. Solomon, M.D.
Human Tissue Staff
Office of Blood Research and Review
Center for Biologics Evaluation and Research (HFM-305)
1401 Rockville Pike

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448

JUN 2 7 2000

Dear Colleague:

The Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) and Center for Devices and Radiological Health (CDRH) are sponsoring an open public meeting on Human Bone Allograft: Manipulation and Homologous Use in Spine and Other Orthopedic Reconstruction and Repair. This meeting is for all interested persons including industry, health professionals, patients and their advocacy groups. This meeting is an opportunity for the public to share scientific data and general information about human bone allografts in relation to the proposed tissue regulations. The meeting is scheduled for:

August 2, 2000
NIH Clinical Center
Building 10, Jack Masur Auditorium
National Institutes of Health
9000 Rockville Pike
Bethesda, MD

The agency is requesting specific information concerning the characteristics of various bone products as they relate to the agency's proposed definitions of minimal and homologous use.

This open public meeting is free of charge, however, registration is required. Additional information may be found on the agency's web site at http://www.fda.gov/cber/scireg.htm. If you have any questions, contact Kathy Eberhart, at 301-827-1317.

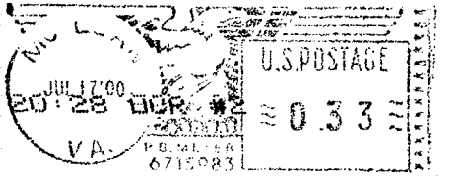
Kathryn C. Zoon, Ph.D.
Director
Center for Biologics Evaluation
and Research

David W. Feigal, Jr., M.D., MPH
Director
Center for Devices and
Radiological Health

Attachment

American Association of Tissue Banks
1350 Beverly Road, Suite 220-A
McLean, Virginia 22101

07/17/00 MD.VA. P&DC 220



Kathy A. Eberhart
Office of Communications, Training & Manufacturers Assistance
Division of Manufacturers Assistance and Training
Manufacturers Assistance & Technical Training Team
Center for Biologics Evaluation & Research (HFM-49)
11400 Rockville Pike
Room 315
Rockville, MD 20857